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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 03/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/604,942	BENTWICH, ITZHAK	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 August 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-20* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Notice to Comply with Sequence Rules

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CRF §§1.821(a)(1) and (a)(2). See, for example, the sequences listed on page 49 and 50. However, this application fails to comply with the requirements of 37 CFR §§1.821 through 1.825 because it lacks any submission of a computer readable form sequence listing, a paper copy for the specification, a statement under 37 CFR §§1.821(f) and (g), and SEQ ID Nos cited along with each sequence in the specification or Figures. Applicants are also reminded that SEQ ID Nos are not required in the Figures per se, however, the corresponding SEQ ID Nos then are required in the Brief Description of the Drawings section in the specification. Applicants are also reminded that a CD-ROM sequence listing submission may replace the paper and computer readable form sequence listing copies. Applicant(s) are given the same response time regarding this failure to comply as that set forth to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or notice of a failure to fully respond to this Office action.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-8, 11-12 and 14, drawn to a bioinformatically detectable novel viral gene, a probe comprising said novel gene, a vector comprising said

novel gene, a kit comprising said vector and a vector inserter and a kit comprising said probe and a gene expression detector, classifiable in class 536, subclass 24.5. (A sequence and a species election is required if this group is chosen)

II. Claims 9 and 10, drawn to a method of inhibiting translation of at least one gene comprising introducing the vector of claim 10 into a cell, classifiable in class 514, subclass 44. (A sequence election is required if this group is chosen)

III. Claim 13, drawn to a method of detecting gene expression using a DNA probe that comprises a bioinformatically detectable novel gene, classifiable in class 436, subclass 6. (A sequence election is required if this group is chosen)

IV. Claims 15 and 16, drawn to an antiviral substance capable of neutralizing RNA comprising complementarily binding the RNA, classifiable in class 536, subclass 24.5. (A sequence election is required if this group is chosen)

V. Claims 15 and 17, drawn to an antiviral substance capable of neutralizing RNA comprising immunologically neutralizing RNA, classifiable in class 424, subclass 137.1. (A sequence election is required if this group is chosen)

VI. Claim 19, drawn to a method of anti-viral treatment comprising neutralizing RNA comprising synthesizing, transfecting and complementarily binding RNA, classifiable in class 514, subclass 44. (A sequence election is required if this group is chosen)

VII. Claim 20, drawn to a method of anti-viral treatment comprising neutralizing RNA comprising immunologically neutralizing RNA, classifiable in class 435, subclass 5. (A sequence election is required if this group is chosen)

The inventions are distinct, each from the other because of the following reasons:

Group I and Group II and III are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group I is drawn to a nucleic acid product that is a bioinformatically detectable novel gene including vectors and kits thereof. Group II and III are drawn to methods of using the nucleic acid product of Group I. Group II is drawn to and reads on a method of treatment and requires inhibition of at least one gene in a cell. Group III is drawn to an assay method of detecting gene expression. In the instant case, the product as claimed can be used in a materially different process of using that product. In regards to groups I and II, the product may be used in a method of hybridization, to detect gene expression. In regards to groups I and III, the product may be used in a method of inhibiting gene expression by inhibiting translation.

Furthermore, search and examination of Group I with either of Groups II or III would impose a serious and undue burden. In the instant case, prior art searches of methods of treatment (or of methods of inhibiting gene expression in vitro) and of methods of detecting gene expression would not be coextensive with a prior art search of the claimed compound(s). Search of each of these inventions would require different key word searches of each method that would necessarily include a search for the distinctive method steps of each that would be different for each and that would not be required in a search of the compound(s). These searches would have to be performed using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and

examination. As such, it would be burdensome to perform search and examination of Group I with either of Groups II or III.

Groups IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group IV is drawn to an antiviral substance capable of neutralizing RNA comprising complementarily binding the RNA. Group V is drawn to an antiviral substance capable of immunologically neutralizing RNA. In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. The invention of group IV operates by complementary binding to RNA. The invention of group V operates by immunologically neutralizing RNA.

Furthermore, searching the inventions of groups IV and V together would impose a serious and undue burden. In the instant case, prior art searches of each composition are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups IV and V together.

Groups VI and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group VI is drawn to a method of antiviral treatment comprising neutralizing RNA comprising complementarily binding the RNA. Group VII is drawn to a method of antiviral treatment comprising immunologically neutralizing RNA. In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. The invention of group VI operates by complementary binding to RNA. The invention of group VII operates by immunologically neutralizing RNA.

Furthermore, searching the inventions of groups VI and VII together would impose a serious and undue burden. In the instant case, prior art searches of each composition are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups VI and VII together.

Groups IV and Group VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group IV is drawn to an antiviral substance capable of neutralizing RNA

comprising complementarily binding the RNA. Group VII is drawn to a method of antiviral treatment comprising immunologically neutralizing RNA. In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. The invention of group IV operates by complementary binding to RNA. The invention of group VII operates by immunologically neutralizing RNA.

Furthermore, searching the inventions of groups IV and VII together would impose a serious and undue burden. In the instant case, prior art searches of the compound and the method would not be coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require a search for the distinct steps of the method that would not be required in a search of the compound. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups IV and VII together.

Groups V and Group VI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Group V is drawn to an antiviral substance capable of immunologically neutralizing RNA. Group VI is drawn to a method of anti-viral treatment comprising neutralizing RNA comprising synthesizing, transfecting and complementarily binding

RNA. In the instant case the different inventions are not disclosed as capable of use together and they have different modes of operation. The invention of group V operates by immunologically neutralizing RNA. The invention of group VII operates by complementary binding to RNA.

Furthermore, searching the inventions of groups V and VI together would impose a serious and undue burden. In the instant case, prior art searches of the compound and the method would not be coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require a search for the distinct steps of the method that would not be required in a search of the compound. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of the inventions of groups IV and VII together.

Groups IV and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group IV is drawn to an antiviral substance capable of neutralizing RNA comprising complementarily binding the RNA. Group VI is drawn to a method of anti-viral treatment comprising neutralizing RNA comprising

synthesizing, transfecting and complementarily binding RNA. In the instant case the product as claimed can be used in a materially different process of using that product which would be a method of hybridization detection of an RNA by complementary binding.

Furthermore, search and examination of Group IV with Group VI would impose a serious and undue burden. In the instant case, a prior art search of the claimed method would not be coextensive with a prior art search of the claimed compound(s). Search of each of these inventions would require a different key word search of the method and would require a search for the distinctive steps of the method that would not be required in a search of the compound(s). These searches would have to be performed using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of Group IV together with Group VI.

Groups V and VII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). Group V is drawn to an antiviral substance capable of immunologically neutralizing RNA. Group VI is drawn to a method of anti-

viral treatment comprising immunologically neutralizing RNA. In the instant case the product as claimed can be used in a materially different process of using that product which would be a method of immunological detection of an RNA.

Furthermore, search and examination of Group V with Group VII would impose a serious and undue burden. In the instant case, a prior art search of the claimed method would not be coextensive with a prior art search of the claimed compound(s). Search of each of these inventions would require a different key word search of the method and would require a search for the distinctive steps of the method that would not be required in a search of the compound(s). These searches would have to be performed using divergent patent and non-patent literature databases. The different searches would then require subsequent in-depth analysis of the unrelated prior art literature, placing a serious and undue burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of Group V together with Group VII.

Groups I-III and Groups IV-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). Groups I-V are relied upon as above. In the instant case the different inventions are not disclosed as capable of use together and they have different functions and effects. Group I functions to provide a bioinformatically novel viral RNA. Group II functions as a method of inhibiting at least one gene. Group III functions as a

method of detecting at least one gene. Groups IV and V each function as an antiviral substance. Groups VI and VII each function as a method of treating viruses.

Furthermore, searching any of the inventions of groups I-III together with either of the inventions of groups IV or V would impose a serious search burden. In the instant case, prior art searches of each composition and of each method are not coextensive. Search of each of these inventions would require different key word searches in divergent patent and non-patent literature databases and would require a search for the distinct steps required by each method that would not be required in a search of the other methods or in a search of the compositions. Each search would then require subsequent in-depth analysis of all relevant prior art literature, placing an undue and serious burden on the Office in terms of both search and examination. As such, it would be burdensome to perform search and examination of any of the inventions of groups I-III together with either of the inventions of groups IV or V.

Claim 15 link(s) inventions of groups IV and V that are antiviral substances. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 15. Claim 18 link(s) inventions of groups VI and VII that are methods of antiviral treatment. The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claim 15. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant

application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an

otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Sequence Election Requirement

In addition to the above restriction requirement, all the groups in the instant application read on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences. For each sequences, the Applicants must elect a single sequence (See MPEP 803.04). It is noted that the multitude of sequence submissions of examination has resulted in an undue search burden if more than one sequence is elected. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement

pursuant to 35 U.S.C. 121 and 36 CFR 1.141 et seq. Examination will be restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction requirement and not a specie election requirement.

Species Election regarding Target Genes

Claims 1-8, 11-12 and 14 generic to the following disclosed patentably distinct species: the target genes. The species (target gene sequences) are independent or distinct because the sequences are unrelated. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (a single target gene that must be the target of the elected gene encoding RNA), even though this requirement is traversed. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Conclusion

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00am-6:30pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D. can be reached on (571) 272-0718. The fax phone

number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). Representatives are available to answer your questions daily from 6 am to midnight (EST). When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center at (800) 786-9199.

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